

We claim:

1. A kit for measuring the thrombin generation in a sample, comprising a lyophilized tissue factor (TF)/phospholipid (PL)-complex and a lyophilized mixture containing a thrombin-substrate and CaCl_2 .
2. The kit according to claim 1, wherein the concentration of TF in the lyophilized TF/PL-complex ranges from about 5 to about 1000 pM.
3. The kit according to claim 1, wherein the concentration of PL in the lyophilized TF/PL-complex ranges from about 1 to about 100 μM .
4. The kit according to claim 1, wherein said TF or at least a functional part thereof is of natural or recombinant origin.
5. The kit according to claim 1, wherein said PL is of natural or synthetic origin.
6. The kit according to claim 1, wherein said PL is selected from the group consisting of phosphatidylserine (PS), phosphatidylcholine (PC), phosphatidylethanolamine (PE) and mixtures thereof.
7. The kit according to claim 6, wherein the weight ratio of PC/PS is in the range of from about 60/40 to about 95/5.
8. The kit according to claim 6, wherein the weight ratio of PC/PS/PE is in the range of from about 60/20/20 to about 78/17/5, based on the total amount of phospholipids.
9. The kit according to claim 1, wherein the thrombin-substrate contains a fluorescent or radioactive label.

10. The kit according to claim 1, further comprising at least one thrombin standard.
11. The kit according to claim 1, wherein the lyophilized TF/PL-complex is immobilized onto a support.
12. The kit according to claim 1, wherein the lyophilized mixture containing a thrombin-substrate and CaCl_2 is immobilized onto a support.
13. The kit according to claim 11 or 12, wherein the support is the inner surface of a vial or wells of an ELISA plate or strip.
14. A process for preparing a lyophilized tissue factor (TF)/phospholipid (PL)-complex, comprising the following steps:
 - (a) preparing by extrusion phospholipid vesicles having a diameter in the range of about 200 to about 300 nm;
 - (b) lyophilizing the phospholipid vesicles to obtain a powder;
 - (c) reconstituting the powder with water for injection and mixing it with a tissue factor;
 - (d) freezing and thawing the mixture obtained in step (c) to form a TF/PL-complex;
 - (e) stabilizing the TF/PL-complex by incubating at about 4°C for about 24 to 72 hours; and
 - (f) lyophilizing the TF/PL-complex.
15. The process of claim 14 wherein, between steps (e) and (f), the TF/PL-complex is diluted to an appropriate "ready to use" concentration.
16. A process according to claim 14, wherein the TF/PL-complex in step (f) is immobilized onto a support by lyophilizing.
17. A process according to claim 16, wherein the support is the inner surface of a vial or wells of an ELISA plate or strip.

18. The process according to claim 14, wherein the TF/PL-complex in the step (f) is lyophilized without any preservatives.
19. A process for preparing a lyophilized mixture containing a thrombin-substrate and CaCl_2 , comprising the following steps:
- (a) dissolving a thrombin-substrate in a suitable solvent;
 - (b) adding CaCl_2 and dissolving the formed precipitate containing the thrombin-substrate and CaCl_2 ; and
 - (c) lyophilizing the mixture containing the thrombin-substrate and CaCl_2 .
20. A process according to claim 19, wherein in step (c) the mixture is immobilized onto a support by lyophilizing.
21. A process according to claim 20, wherein the support is the inner surface of a vial or wells of an ELISA plate or strip.
22. A method for measuring the thrombin generation in a sample, comprising the steps of:
- (a) providing a lyophilized tissue factor (TF)/phospholipid (PL)-complex and a lyophilized mixture containing thrombin-substrate and CaCl_2 ;
 - (b) contacting the sample with said lyophilized TF/PL-complex and said lyophilized mixture containing thrombin-substrate and CaCl_2 ; and
 - (c) measuring the thrombin generation in said sample.
23. The method according to claim 22, wherein the sample is selected from the group consisting of whole blood, plasma and mixtures containing purified proteins from natural, synthetic or recombinant origin having haemostatic activity.